REIMBURSEMENT BASICS

Learning Objectives

After reading this brief, you will be able to…

I. Understand the basics of the US healthcare system and how healthcare is reimbursed
II. Appreciate how coding, coverage, and payment work in the US Medicare system
III. Take the steps necessary to perform a high-level reimbursement analysis for an early-stage health technology

Getting Started

Within the health technology sector, reimbursement is a catch-all term for describing how things are paid for when a third-party payer (like an insurance company) is involved. This includes payments for the technology itself, the providers who use it, and the facilities where it is deployed. It's critically important to have a general understanding of these basic economics since most health technology innovators would say that obtaining reimbursement is the single biggest obstacle they face in getting their technology into patient care.

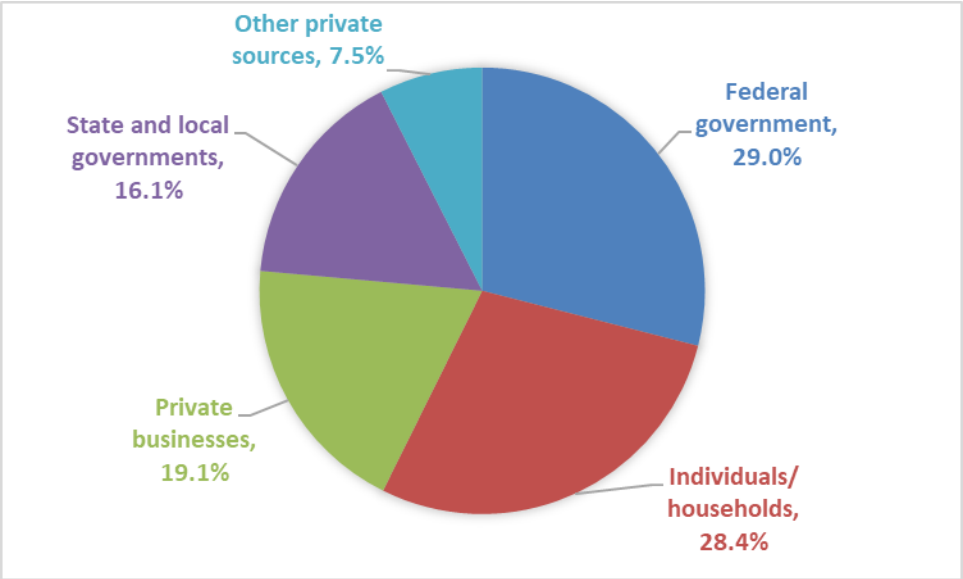
To say that the system of payments in healthcare is complex would be a huge understatement! The good news is that if you understand the fundamentals outlined in this brief, you'll know enough to anticipate potential reimbursement issues with your project. You'll also know how to engage with reimbursement experts and get help preparing a reimbursement analysis to support the launch of your technology.

The System

The US spends much more on healthcare per capita than any country in the world. The country's total annual expenditure reached more than $4 trillion in 2020 and is projected to climb to more than $6 trillion by 2028.[1] This represents a large and growing percentage of the country's gross domestic product (projected to rise from 17.7% in 2017 to 19.7% by 2028[2]), which is a source of enormous concern to economists, politicians, and business leaders alike. Many researchers agree that the biggest driver of the increase in healthcare costs is the introduction of new health technologies and other novel treatments into the healthcare system.[3] Of course, this is not to say that new technology is intrinsically a bad thing – just expensive.

Overall, healthcare in the US is paid for via a combination of government programs, private businesses (including insurance companies like Aetna, Anthem, and UnitedHealthcare, as well as self-insured employers), and individual self-pay (sometimes called out-of-pocket payments) as shown in Figure 1.

Figure 1 – Total Health Spending by Category[5]



The largest government payer is the Centers for Medicare and Medicaid Services (CMS, with only one "M"). CMS processes over one billion payment claims per year.[4] Its flagship program is Medicare, which is federally funded and administered. Medicare covers people who are 65 or older, certain young people with disabilities, and those with chronic kidney disease requiring long-term dialysis or kidney transplantation. CMS also supports the Medicaid program, which is based on income (rather than age or specific conditions) and provides health coverage to low-income families and individuals. Medicaid is jointly funded by CMS and each state, but managed at the state level. The individual states have considerable control over the design and administration of their Medicaid programs, which leads to significant variability across the country.

Beginning in 2010 with the passage of the Affordable Care Act (colloquially known as "Obamacare"), there has been a shift away from traditional fee-for-service models that enabled providers to bill based on the quantity – not quality – of healthcare services provided to patients. An alternative approach, that now is being more widely adopted, is value-based healthcare. It explicitly attempts to reward the quality of care while taking into account cost-effectiveness (i.e., the relationship between the healthcare outcomes achieved and the money spent to realize them). See the toolkit called Understanding Health Economic and Commercial Value for more information.

In an effort to support the move to value-based healthcare, in 2012 CMS began providing incentives for the formation of accountable care organizations (ACOs). ACOs voluntarily enable independent physician groups, hospitals, and insurers to join forces in caring for a defined population of Medicare recipients for a specified period of time. In exchange for delivering more coordinated care while emphasizing cost containment, the ACO shares in the savings realized by CMS.

A related value-focused model is called an integrated delivery network (IDN). IDNs aggregate all of the parties involved in the provision and payment of healthcare for a defined population into a self-contained ecosystem. By actively managing all aspects of its members' healthcare experience, from prevention through chronic care management, IDNs seek to optimize the cost effectiveness of

the care they deliver across the affected population. Examples of IDNs include Kaiser Permanente in the West and Geisinger Health System in the East.

Payment systems outside the US vary widely from country to country. Many developed nations have some form of universal healthcare (i.e., a government-led single-payer system), often with a secondary layer of private coverage for those who can afford it.

How Medicare Works

There's a saying in healthcare that "Medicare leads, and private payers follow."[6] While this may no longer apply across the board, it's important to understand how Medicare works because it's such a dominate player in the US healthcare system.

Medicare is divided into four parts:

I. Part A – For hospital stays and care in skilled nursing facilities
II. Part B – For physician services, outpatient care, medical supplies, and preventive services
III. Part C – Also called Medicare Advantage, which allows beneficiaries to pay into a plan that offers them enhanced healthcare options
IV. Part D – For prescription drug coverage

Funding for Medicare is provided through federal taxes, payroll taxes, and premiums paid by beneficiaries. In total, Medicare accounts for approximately 15% of federal spending each year.[7] There's significant national concern that, based on current projections, Medicare will run out of funding by 2026.

The Medicare system is structured to reimburse both providers (physicians and other health professionals) and facilities (hospitals or ambulatory facilities). There are three essential components to the system: coding, coverage, and payment.

Coding

In order for a Medicare claim to be paid, providers and facilities must submit claims to CMS using standardized codes. These codes provide a shorthand way of describing what was done, how it was done, and why (what was the underlying condition treated?). Hospitals and medical practices employ specially-trained accounting staff who are responsible for identifying the right codes for every patient encounter and submitting these to CMS for reimbursement.

Different systems of codes are used depending on where the care was delivered.

- **For inpatient care:**
  The set of codes used for patients treated in the hospital is called ICD-10 (International Classification of Diseases, 10th revision). This system is in turn divided into two subsets of codes.

  Clinical Modification or ICD-10-CM codes describe the primary applicable diagnoses for a patient.

  If there was a procedure done in the hospital, that is labelled and billed for using the Procedure Coding System or ICD-10-PCS codes.

  All told, there are over 140,000 ICD-10 diagnosis and procedure codes.

- **For outpatient care:**
  The same ICD-10-CM system is used for the coding of outpatient diagnoses. However, for outpatient procedures or services, there is a different system called HCPCS (Healthcare Common Procedure Coding System). This, in turn, has two levels of codes:

  Level 1 codes are called Current Procedural Terminology or CPT codes and are used to bill for procedures or services provided by hospitals or physicians on an outpatient basis, or by other outpatient facilities such as ambulatory surgical centers (ASCs).

  HCPCS Level II codes are for medical products, supplies, or services not covered by a CPT code, such as ambulance transport or durable medical equipment.

These coding systems and what providers use them are summarized in Table 1.[8]

Provider	Setting	Procedure Code	Diagnosis Code
Hospitals	Inpatient	ICD-10-PCS	ICD-10-CM
Hospitals	Outpatient	CPT/HCPCS Level I	
Ambulatory Surgical Centers	Outpatient		
Physicians	Outpatient (facility/office)		
Various providers of products, services, and supplies	Outpatient	HCPCS Level II	

At an early stage of your project, you should try to get a solid understanding of whether or not your technology or procedure is likely to fit under an existing code within the appropriate coding system. If it aligns with an existing code that has already been approved for similar products or procedures, your project is at a tremendous advantage since reimbursement could potentially begin immediately following FDA authorization. If not, applying for a new code is a complicated, time-consuming, and expensive process. Accordingly, it could be years before your technology or procedure is eligible for reimbursement.

Whether or not your innovation is covered by an existing code will ultimately be up to CMS to decide. However, you can get a reasonably good indication by looking carefully at the language of the relevant section of the coding policy. CMS' website provides a database and wealth of additional resources that can help you gain some preliminary insights.

Coverage

Once coded, CMS will only approve a Medicare claim if it's deemed to be an appropriate treatment for that patient's condition and has been provided in an appropriate setting, according to Medicare's predetermined coverage policies. Stated another way, every new technology that's targeted at the Medicare population must receive a coverage decision from CMS that stipulates under what specific conditions it will be reimbursed.

To make things even more complex, coverage policies are national in some cases and local in others. A national coverage decision (NCD) is made centrally by CMS. A local coverage decision (LCD) is made by CMS divisions across the country that are empowered to make coverage decisions appropriate for their region. A company with a new technology or procedure must decide whether to apply for an NCD or LCD. NCDs can provide an efficient pathway to nationwide coverage, but they're binding decisions that cannot be overruled at the local level. LCDs are less

risky, but require significantly more work since they must be pursued separately for each region. The right approach is highly dependent on the specific innovation and should be made in consultation with a reimbursement expert.

Payment

After coding and coverage, there's still one more important component in seeking reimbursement for a Medicare claim – payment. Unfortunately, the structure of how CMS pays providers and facilities introduces additional systems and codes that innovators must understand.

For inpatient hospital payments, the codes are called Medicare Severity Diagnosis-Related Groups (MS-DRGs). This system excludes physician services but lumps together all other hospital costs, including tests, procedures, devices, operating room, nursing time, etc. into a **single** payment. It's important to understand this because your new procedure or technology will fall under a DRG, and hospitals will be incentivized (or not) to use it based on:

- How substantial the payment is under that DRG
- Whether the addition of the new procedure or technology leads to a net improvement or reduction in the hospital's bottom-line income for that DRG

The level of the payment is determined based on the diagnoses for that patient and any complications or other patient-related factors that make the episode of care longer or more complex. The payment is also adjusted to take into account regional differences in labor costs and other conditions.

For hospital outpatient services – where the care is delivered in a hospital but the patient does not stay overnight – there is a separate Ambulatory Payment Classification (APC) system. With this system, the codes and corresponding payment is based on the procedure that was performed (rather than the diagnosis). A single outpatient encounter can result in more than one APC payment.

Care delivered in freestanding ambulatory surgical centers (ASCs) is considered separately from hospital outpatient procedures and Medicare payments to these facilities are made using the ASC fee schedule.

Physician services are paid using the Medicare Physician Fee Schedule (MPFS), which translates the relevant CPT code into a payment amount. It's helpful to spend extra time understanding how physician payments work in your need area since financial incentives to physicians will be an important driver of the uptake of your eventual solution. Physician payments vary depending on whether the service was performed inside or outside the hospital and, again, on the geographic region. The level of payment is set and updated through a complicated process that involves a collaboration between CMS and expert committees from the American Medical Association (AMA). The resulting fee scale is called the Resource Based Relative Value System (RBRVS). You may hear physicians speak about their RVUs (relative value units) – an RVU is the basic unit of measurement in this system by which they are paid. More complicated procedures or services are assigned higher RVUs and are reimbursed at a higher level.

Finally, devices that are used in the home setting for a longer period of time – for example, home oxygen systems or wheelchairs – are paid for through the durable medical equipment (DME) fee schedule, which sometimes is based on monthly rental fees or on the gradual acquisition of the technology.

Table 2 adds this payment construct to the information shown in Table 1.[9]

Provider	Setting	Payment	Procedure Code	Diagnosis Code
Hospitals	Inpatient	MS-DRG + MPFS	ICD-10-PCS	ICD-10-CM
Hospitals	Outpatient	APC	CPT/HCPCS Level I	
Ambulatory Surgical Centers	Outpatient	ASC Fee Schedule		
Physicians	Outpatient (facility/office)	MPFS		
Various providers of products, services, and supplies	Outpatient	DME Fee Schedule	HCPCS Level II	

Private Insurance

There are many hundreds of insurance companies in the US and it is a huge, mostly for-profit industry (with revenues over $1 trillion). Typically, private insurance policies are offered to individuals through the companies they work for (known as employee-sponsored health insurance). The company selects and purchases one or more plans (called group plans) and offers these to employees and their dependents. Employees typically pay for some portion of the cost of the policy, but the company pays the majority.

On the provider side, there are two main types of health organizations with respect to contracting with insurance companies. These won't influence your project planning at this stage in the process, but it's important to understand the basic system.

- Health Maintenance Organizations (HMOs) are consortiums of physicians and hospitals that negotiate a contract with insurance companies as a network.
- Preferred Provider Organizations (PPOs) are similar in structure but are generally less restrictive in terms of the providers and services that are accessible to members of the network. The disadvantage of PPOs is that the insurance is more costly and typically has a higher level of copayments (the amount that the patient pays out-of-pocket before insurance begins to cover).

In many cases, private insurance companies tend to follow Medicare's lead in their coverage policies and the structure of their reimbursement. However, the actual payment levels from private insurers are typically higher than payments by Medicare (almost double, on average). And, although there's overlap in the coding, coverage, and payment categories between private insurers and Medicare, there are many individual variations by private insurers (e.g., carve-out arrangements and alternate payment structures). This leads to an extraordinary degree of complexity for all concerned. Hospitals and physician groups need to understand and utilize different systems for reimbursement, depending on the insurer. Additionally, companies developing new technologies and procedures need to establish coverage and payment with the different private insurance companies on a one-by-one basis, which is extremely time-consuming and expensive.

For the purposes of your project in the early stages, it's usually sufficient to get started by understanding the likely Medicare payment scenario and waiting to dive into the nuances of private insurance reimbursement until you get further along. However, some projects may not be relevant to the Medicare population (for example, pediatric technologies) so, in these cases, it will be necessary to access to private insurance schedules.

Self-Pay

Certain health technologies are not reimbursed by CMS or private insurers and, instead, are paid for directly by patients. For example, the Lully technology for reducing night terrors in children (see the toolkit called Becoming an Expert in Your Need through Research) is an example of this type of technology – as are many of the health technologies sold in drug stores such as blood pressure cuffs and thermometers. Given the complexities of Medicare and private insurance reimbursement, it may seem attractive to pick a project that is purposely intended for self-pay. That can, in fact, be a good strategy, but you should keep two other considerations in mind. First, consumers tend to be highly cost-conscious when it comes to healthcare and aren't likely to pay as much for a technology or procedure as what can be earned once reimbursement is obtained from insurance. Second, by utilizing a CMS/insurance reimbursement pathway, a company can take advantage of the vast machinery for coding and submitting claims by the providers rather than investing time and energy into getting individual consumers to make a buying decision.

One final note is that self-pay mechanisms generally represent a larger portion of reimbursement in countries outside the US. See the toolkit called Business Model Basics for more information on non-reimbursement payment pathways.

First Steps for Your Project

A full reimbursement analysis is a major undertaking and requires a great deal of research and specialized expertise. That said, there's some important work you can do for an early-stage innovation project that will help you with screening and selecting which solution concepts to move forward with, provide you with important directional information, and equip you with smart questions when you do get the chance to engage with a reimbursement consultant. See Table 1 for an overview of the key steps you can take.[10]

Topic	Description
Payer mix	Identify the primary payer(s) and mix of services by payer.
Location of procedure	Describe the setting in which the new device would be utilized and/or the procedure would be performed.
Coverage decisions and technology assessment by Medicare, private payers, and/or health technology assessment agencies	Summarize the coverage decisions for comparable devices and/or procedures, including how long it took to achieve reimbursement and any constraints or exceptions that may affect coverage.
CPT code and payment amount	Define the appropriate CPT code and patient copayment under Medicare or determine if a new code is needed.
MS-DRG, APC, and/or other codes and payment amounts	Define the appropriate DRG, APC, or other code (e.g., HCPCS Level II) and patient copayment under Medicare or determine if a new code is likely to be required.
Facility costs	Summarize the anticipated facility-related costs for the device and/or procedure.
Number of procedures	Summarize the number of procedures performed and reimbursed, reimbursement per procedure, and payer mix.

The video called Tips for Doing Online Reimbursement Research will walk you through key steps and some important web-based resources for initiating your reimbursement analysis.

The most important point is to identify whether there is a similar technology or procedure that already has reimbursement coding and then determine whether the language used to describe that technology or procedure accurately covers your new approach. In order to do this, you need to understand where the procedure will be done or the technology will be used – and look up the corresponding diagnosis, procedure, and payment codes. Check out the video called Seeking Reimbursement Under an Existing Code for some additional tips based on one team's experience.

If your new technology or procedure is not covered by existing codes, you can still get a sense for the reimbursement landscape by looking at examples that are in your same clinical area and are close in terms of complexity and patient profile. Many medical device companies publish reimbursement guides for their technologies that are on the market, and these can prove helpful in gaining an initial understanding of applicable codes, current coverage, and existing payments. Watch the video called Pursuing a New Reimbursement Code for a relevant case example.

BOX 1

Performing Initial Reimbursement Analysis

Shortly after completing their regulatory analysis (as described in the toolkit called Regulatory Basics, the Tympani team began investigating how they might make money with their inflatable ear mold technology. Their device was specifically designed for a pediatric population, so they immediately recognized that their payer mix would differ from that of many other medical technologies. Medicare would be out of consideration, but Medicaid was still in play via the Children's Health Insurance Program (CHIP).

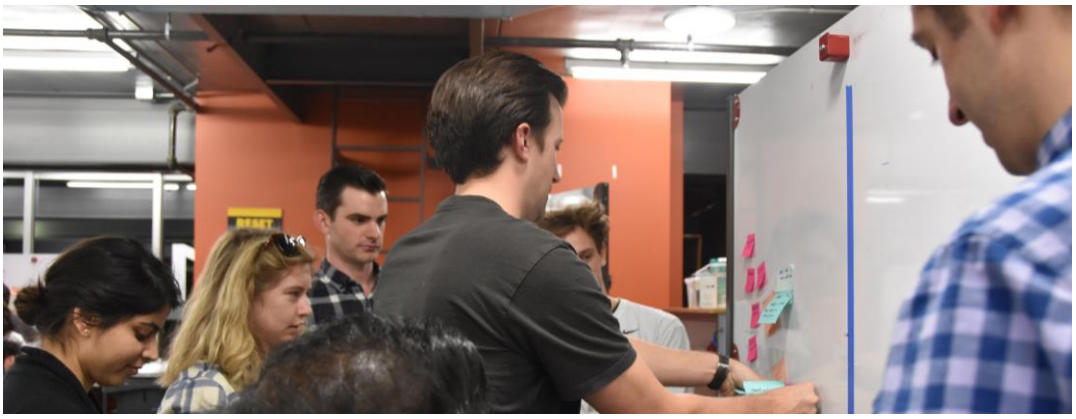
Using 2019 data from the Kaiser Family Foundation, the team found that approximately 55% of children in the US had private insurance, 40% were covered by CHIP or other public programs, and 5% were uninsured. From validation interviews, Tympani estimated that 80% of the private insurance plans would cover the device. Thus, they estimated that their payer mix would be approximately 45% private insurance, 40% CHIP, and 15% cash pay.

The Tympani device would be custom-made for each child based on a mold created in the audiology clinic. Accordingly, the team determined that it would make sense to route the billing through the audiologist's office. Existing custom earmolds were reimbursed via HCPCS code V5264 (earmold/insert, not disposable, any type), so they initially planned to pursue a reimbursement strategy based upon this coding. Conversations with audiologists and parents of patients indicated that Medicaid reimbursed for pediatric ear molds at $35 per mold ($70 per pair), while private insurers (when they covered the devices) typically reimbursed at closer to $50 per mold. Some insurance plans did not cover custom ear molds so, in those situations, the costs were left to parents to pay out of pocket.

Tympani planned on using the existing reimbursement code to hasten the market uptake of their device. However, they also recognized that, if their device worked as intended, they would be leaving an immense amount of value on the table. Because of its inflatable design, a single Tympani earmold could grow with the patient, removing the need for constant replacements and their associated costs to payers and patients. The team estimated that the average patient with bilateral hearing loss needed 20 traditional

earmolds between the ages of 0 and 7, but that same patient would only require four Tympani molds.

How to capture this value became the central question of Tympani's payment analysis and underlying business model (see the toolkit called Business Model Basics. The team felt confident with their decision to pursue rapid commercialization using existing reimbursement codes. However, they recognized that they were operating in a small market. In order to create a viable business, they would either need to charge premium prices or quickly pursue an alternate reimbursement strategy. But first, they needed to prove their device could be valuable to the relevant stakeholders – most notably, the payers.



Credits

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Notes

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[5] National Health Expenditure (NHE) Fact Sheet, CMS.gov, 2019, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (February 3, 2021).

[6] James Chambers, et al., "Private Payers Disagree with Medicare Over Medical Device Coverage About Half the Time," *Health Affairs*, August 2015, https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0133 (February 4, 2021).

[7] Juliette Cubanski, Tricia Neuman, and Meredith Freed, "The Facts on Medicare Spending and Financing," Kaiser Family Foundation, August 20, 2019, https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/ (February 4, 2021).

[8] Yock, et al., *Biodesign: The Process of Innovating Medical Technologies,* Second Edition, Cambridge University Press, 2015.

[9] Ibid.

[10] Ibid.